Remarks

Applicant, herein, has amended claims 1, 3-6, 9, 10, 19 and 21; has canceled claims 7, 8, 13-18 and 20; and has added new claims 27 and 28. Nineteen (19) claims remain pending in the application, claims 1-6, 9-12, 19 and 21-28, of which claims 1 and 21 are independent. Applicant respectfully requests reconsideration of the pending claims, in view of the claim amendments above and comments below.

Summary

Amendments have been made to the claims to distinguish over the prior art, and particularly, over US 6,464,687 (Ishikawa et al.). Once amended, the remaining independent claims (claims 1 and 21) cover implanting a device to apply electrical stimulation to cause hypoperfusion ("decreased blood flow through organs or tissue") or hyperperfusion ("increased blood flow") to keep or direct delivered medications, respectively, to a certain location within the body. The Examiner correctly points out that Ishikawa et al. disclose an implantable system capable of delivering drugs and providing electrical stimulation to tissue, and further, a system able to "actuate a response [in response to] measurements of luminal diameter and fluid flow rate within the vessel lumen" (col. 13, lines 26-30). Yet, while Ishikawa's system *may be capable* of causing hypoperfusion or hyperperfusion, there is no teaching or suggestion in Ishikawa et al. to do this. For instance, there is no teaching or suggestion how (or why) one of skill in the art would use the Ishikawa et al. system to cause hypoperfusion or hyperperfusion. Further, while Ishikawa et al. teach that their device "provides an actuator function to stimulate the tissues into which drugs are to be released" (col. 29, lines 35-36), there is no discussion of what type of stimulation should be used or why, and certainly no suggestion that the stimulation should be used to cause hypoperfusion or hyperperfusion to keep or direct the drugs to a certain location within the body. As explained further below, a person of ordinary skill in the art would not have been motivated by Ishikawa et al., alone or in combination with the other cited art, to implant a device to apply electrical stimulation to cause hypoperfusion or hyperperfusion to keep or direct drugs to a certain location within the body, which is claimed in amended independent claims 1 and 21.

Claim Rejections - 35 USC § 102

In paragraph 1 of the Office Action mailed October 23, 2003, claims 1, 2, 6-15, 17, 19-22 and 26 were rejected under 35 U.S.C. 102(e) as anticipated by Ishikawa et al. (US 6464687). After entry of the present amendment, two independent claims remain in the application: claims 1 and 21. Independent claim 13 has been canceled.

To overcome this rejection, applicant has herein amended independent claims 1 and 21 to focus on an embodiment described in detail in the specification; see, for instance, page 2, line 30 – page 3, line 2; page 4, lines 7-13; page 11, lines 21-31; page 12, lines 6-14; page 24, line 27 – page 26, line 5 describing FIG. 7; and page 26, line 26 – page 27, line 13. Claim 1 now covers implanting a device to apply electrical stimulation in a first area of a patient in order to modulate circulatory perfusion in a second area that is targeted for medication delivery, and modifying the electrical stimulation to cause hypoperfusion ("decreased blood flow through organs or tissue" (page 3, lines 8-9)) to restrict perfusion of the medication in the second area. Claim 21 now covers implanting a device to apply electrical stimulation in a first area of a patient in order to modulate circulatory perfusion in a second area that is targeted for to receive medication delivered to a third area, and modifying the electrical stimulation to cause hyperperfusion ("increased blood flow" (page 3, line 7)) to focus the medication in the second area.

After amendment, claims 1 and 21 incorporate, in part, limitations from the canceled portions of claims 9 and 10, respectively, which claims were considered anticipated by Ishikawa. In view of the remarks presented hereafter, such alleged anticipation of claims 9 and 10 is respectfully traversed.

MPEP 2131 states:

> To anticipate a claim, the reference must teach every element of the claim.

Applicants' representative has carefully read Ishikawa et al, and respectfully submits that Ishikawa et al. do not show "applying [a] stimulus...to modulate circulatory perfusion in [an] area of the patient" (see original claim 1, from which original claims 9 and 10 depended) "in coordination with delivery of a medication...target[ing the area] to receive the medication" (see original claim 8, from which original claims 9 and 10 depended) "wherein the stimulus is applied to cause hypoperfusion" (see original claim 9) or "wherein the stimulus is applied to cause hyperperfusion" (see original claim 10).

MPEP 2131 further states:

> "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

As the Examiner points out, Ishikawa et al. state at col. 13, lines 27-30 that:

> The actuators may contain a piezoelectric driver attached to a ball surface for ultrasound generation and control for measurements of luminal diameter and fluid flow rate within the vessel lumen.

The piezoelectric driver is used for "generation and control" of ultrasound that is used for measurements of luminal diameter and flow rate. While it is also true that Ishikawa's system can "actuate a response" (col. 13, line 26) to a "measure [of] various parameters" (col. 13, line 24), including, presumably, a measure of luminal diameter and flow rate, there is no teaching or suggestion in Ishikawa to use a stimulus to *cause* modulation of circulatory perfusion, or to create hypoperfusion or hyperperfusion.

Further, while Ishikawa et al. teach that their device "provides an actuator function to stimulate the tissues into which drugs are to be released" (col. 29, lines 35-36), there is no discussion regarding why one would want to do this, what might result, what type of stimulation should be used or why, or any examples of this device function. There is nothing in Ishikawa that would teach or suggest to one of skill in the art to use, or how to use, the Ishikawa device to apply stimulation in coordination with delivery of a medication to cause hypoperfusion or hyperperfusion in an area targeted to receive a medication. Thus, Ishikawa does not show "the identical invention...in as complete detail as is contained in" original claims 9 and 10.

As **claim 1** has been amended to incorporate additional limitations, including limitations from original claim 9 (and the claims from which claim 9 depended) that applicant believes are allowable for the reasons stated above, it is believed that claim 1 has been placed in condition for allowance. Similarly, independent **claim 21** has been amended to incorporate additional limitations, including limitations from original claim 10 (and the claims from which claim 10 depended) that applicant believes are allowable for the reasons stated above, and thus believes that independent claim 21 has been placed in condition for allowance. Acknowledgement of the same is earnestly solicited.

In the first paragraph of the Office action mailed October 23, 2003, **claims 2 and 6-12**, which depend on claim 1, were also rejected as anticipated by Ishikawa et al. Claims 7 and 8 have been canceled, as their subject matter has been incorporated into amended claim 1. Claims 6 and 10 have been amended to depend from independent claim 21, so should be allowable for the same reasons given above in support of currently amended claim 21. For the remaining of these claims, claims 2, 9, 11 and 12, this rejection is overcome by way of the present amendment for the same reasons given above in support of currently amended claim 1, upon which claims 2, 9, 11 and 12 depend.

In the first paragraph of the Office action, independent **claim 13 and claims 14, 15, 17, 19, and 20**, which depend on claim 13, were also rejected as anticipated by Ishikawa et al. Claims 13-15, 17 and 20 have been canceled, so this rejection is now moot relative to these claims. Claim 19 has been amended to depend from independent claim 21, so should be allowable for the same reasons given above in support of currently amended claim 21.

In the first paragraph of the Office action, **claims 22 and 26**, which depend on claim 21, were also rejected as anticipated by Ishikawa et al. This rejection is overcome by way of the present amendment for the same reasons given above in support of currently amended independent claim 21, upon which claims 22 and 26 depend.

Claim Rejections - 35 USC § 103

In paragraphs 2 and 3 of the Office Action mailed October 23, 2003, **claims 3 and 4** were rejected under 35 U.S.C. 103(a) as unpatentable (obvious) over Ishikawa et al (US6464687) in view of Garfield et al (US6356777). This rejection is overcome by way of the present amendment for the same reasons given above in support of currently amended claim 1, upon which claims 3 and 4 depend.

In paragraph 4 of the Office Action, **claims 5 and 25** were rejected under 35 U.S.C. 103(a) as unpatentable (obvious) over Ishikawa et al (US6464687) in view of Hobbs et al (US5916154). Claims 4 and 5 have been canceled. For claim 5, this rejection is overcome by way of the present amendment for the same reasons given above in support of currently amended claim 1, upon which claim 5 depends. For claim 25, this rejection is overcome by way of the present amendment for the same reasons given above in support of currently amended claim 21, upon which claim 25 depends.

In paragraph 5 of the Office Action, **claims 16 and 18** were rejected under 35 U.S.C. 103(a) as unpatentable (obvious) over Ishikawa et al (US6464687) in view of Keogh et al (US6447443). Claims 16 and 18 have been cancelled, making this rejection moot.

In paragraph 6 of the Office Action, **claims 23 and 24** were rejected under 35 U.S.C. 103(a) as unpatentable (obvious) over Ishikawa et al (US6464687) in view of Kieval et al (US6073048). This rejection is overcome by way of the present amendment for the same reasons given above in support of currently amended independent claim 21, upon which claims 23 and 24 depend.

New claims 27 and 28 are presented herein. Claims 27 and 28 are patterned after claims 3 and 4, respectively, but depend from independent claim 21, rather than independent claim 1. New claims 27 and 28 should be allowable for the same reasons given above in support of currently amended independent claim 21, upon which claims 27 and 28 depend.

After amendment as provided herein, all pending claims depend directly or indirectly from independent claim 1 or 21. As such, applicants respectfully request consideration of independent claims 1 and 21, and their dependent claims, in light of these remarks and the related claim amendments.

Drawings

In paragraph 7 of the Office Action mailed October 23, 2003, FIGS. 5 and 6 were objected to under 37 CFR 1.83(a) because the rectangular boxes were not labeled as described in the specification (FIG. 6) or were labeled with acronyms that are not commonly understood (FIG. 5). FIGS. 5 and 6 are corrected herein by replacement of acronyms in FIG. 5 with full names and by labeling of FIG. 6 as described in the specification. Attached are replacements for the sheets showing FIG. 5 and FIG. 6.

Specification

In paragraph 8 of the Office Action mailed October 23, 2003, the disclosure was objected to because on page 25, line 25, "FIG. 9" should have been --FIG. 7--. By way of the present amendment, this correction has been made.

Information Disclosure Statement

In paragraph 9 of the Office Action mailed October 23, 2003, the Examiner indicated that references were found in the case without an associated PTO-1449.

The references provided for the subject application were filed in two IDSs, which were reviewed by the Examiner, as the two related PTO-1449s were initialed and attached to the October 23, 2003 Office action. There has not been a third IDS submitted for this application.

In view of the foregoing remarks and amendments, it is respectfully submitted that the rejections have been overcome and that the previously-rejected pending claims and the newly-submitted claims are in condition for allowance. An indication of allowability of all pending claims, claims 1-6, 9-12, 19 and 21-28, is earnestly solicited.

Respectfully Submitted,

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Date

Laura Haburay Bishop
Reg. No. 47,424

Please direct all written inquiries to:
Bryant R. Gold
Advanced Bionics Corporation
12740 San Fernando Road
Sylmar, CA 91342

Please direct all telephone inquiries to:
Laura Haburay Bishop
Telephone: (661) 362-1906
Fax: (661) 362-1507

Attachments: Replacement sheet for FIG. 5 (sheet 6/8)
Replacement sheet for FIG. 6 (sheet 7/8)